

AMENDMENT TO THE CLAIMS

Please amend the claims without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows.

In the Claims:

1. (Currently amended) A topical patch comprising
a therapeutic compound-impermeable backing layer,
a self-adhesive amine-resistant polysiloxane matrix ~~based on polysiloxanes~~ containing at least 1%
by weight, ~~preferably at least 2% by weight, more preferably at least 3% by weight, most~~
~~preferably at least 5% by weight,~~ of the therapeutic compound
wherein the polysiloxane matrix is a mixture of a polysiloxane of medium tack and a
polysiloxane of high tack and the therapeutic compound is capsaicin or a capsaicin
analog or mixture thereof, and
a protective film to be removed before use,
in which
 - a. the matrix contains liquid microreservoir droplets comprising an amphiphilic
solvent, in which the therapeutic compound is dissolved, and
 - b. the concentration of the therapeutic compound in the microreservoir droplets is
between 20 and 90% by weight of the saturation concentration
wherein the amphiphilic solvent is a butanediol, 1,3-butanediol, dipropylene
glycol, tetrahydrofurfuryl alcohol, diethylene glycol dimethyl ether,
diethylene glycol monoethyl ether, diethylene glycol monobutyl ether,
propylene glycol, dipropylene glycol, carboxylic acid esters of tri- and
diethylene glycol, polyethoxylated fatty alcohols of 6 - 18 C atoms or
2,2-dimethyl-4-hydroxymethyl-1,3-dioxolane, or mixtures of these
solvents
wherein the therapeutic compound is capsaicin or a capsaicin analog or a mixture thereof.
2. (Original) The topical patch as claimed in claim 1, in which the therapeutic compound is
capsaicin.
3. (Original) The topical patch as claimed in claim 1, in which the concentration in the therapeutic
compound in the microreservoir droplets is between 40 and 70% by weight of the saturation
concentration.

4. (Currently amended) The topical patch as claimed in claim 1, in which the amphiphilic solvent is ~~a butanediol, such as 1,3-butanediol, dipropylene glycol, tetrahydrofurfuryl alcohol, diethylene glycol dimethyl ether, diethylene glycol monoethyl ether, diethylene glycol monobutyl ether, propylene glycol, dipropylene glycol, carboxylic acid esters of tri- and diethylene glycol, polyethoxylated fatty alcohols of 6-18 C atoms or 2,2-dimethyl-4-hydroxymethyl-1,3-dioxolane, or mixtures of these solvents.~~
5. (Original) The topical patch of claim 4 wherein the solvent is diethylene glycol monoethyl ether.
6. (Original) The topical patch as claimed in claim 1, in which the microreservoir droplets comprise a viscosity-increasing additive dissolved in the solvent.
7. (Original) The topical patch as claimed in claim 6, in which the viscosity-increasing additive is a cellulose derivative or a high molecular weight polyacrylic acid.
8. (Original) The topical patch of claim 7, in which the ~~viscosity-increasing~~ ~~viscosity-increasing~~ additive is ethylcellulose or hydropropylcellulose.
9. (Currently amended) The topical patch as claimed in claim 1, in which the proportion of the microreservoir droplets in the matrix is less than 40% by weight, based on the total weight of the matrix preferably less than 35% by weight, in particular between 20 and 30% by weight.
10. (Currently amended) The topical patch as claimed in claim 1, in which the self-adhesive amine-resistant polysiloxane matrix contains at least 3% of the therapeutic compound the proportion of the microreservoir droplets in the matrix is less than 35% by weight, based on the total weight of the matrix ~~the self-adhesive matrix comprises an amine resistant polysiloxane.~~
11. (Currently amended) The topical patch as claimed in claim 10, in which the self-adhesive amine-resistant polysiloxane matrix contains at least 5% of the therapeutic compound the proportion of the microreservoir droplets in the matrix is between 20 and 30% by weight, based on the total weight of the matrix ~~the self-adhesive matrix comprises a mixture of a polysiloxane of medium tack and a polysiloxane of high tack.~~

12. (Original) The topical patch as claimed in claim 10, wherein the matrix contains from about 0.5 to about 5% by weight of a silicone oil.
13. (Currently amended) The topical patch as claimed in claim 1, in which the matrix comprises
5 – 10% by weight of capsaicin or a capsaicin analog,
10 – 25% by weight of diethylene glycol monoethyl ether,
0 – 2% by weight of ethylcellulose,
0 – 5% by weight of silicone oil, and
58 – 85% by weight of self-adhesive polysiloxane and the coating weight of the matrix is between
30 and 200 g/m², ~~preferably between 50 and 120 g/m².~~
14. (Currently amended) The topical patch as claimed in claim 1, in which the matrix consists essentially of
5 – 10% by weight of capsaicin or a capsaicin analog,
10 – 25% by weight of diethylene glycol monoethyl ether,
0 – 2% by weight of ethylcellulose,
0 – 5% by weight of silicone oil, and
58 – 85% by weight of self-adhesive polysiloxane and the coating weight of the matrix is between
~~30 and 200 g/m², preferably between 50 and 120 g/m².~~
15. (Currently amended) The patch as claimed in claim 1 ~~to 14~~, in which the backing layer consists of a polyester film 10 – 20 µm thick.
16. (Original) The topical patch as claimed in claim 1, in which the backing layer consists of an ethylene-vinyl acetate copolymer.
17. (Currently amended) ~~The use of a topical patch as claimed in claim 1~~ A method for the treatment of neuropathic pain which comprises administering the topical patch of claim 1 to a patient in need thereof.
18. (Currently amended) The topical patch as claimed in claim 11, in which the microreservoir droplets comprise a viscosity-increasing additive dissolved in the solvent 1 for use in the treatment of neuropathic pain.

19. (Currently amended) ~~A method for the treatment of neuropathic pain, in which a topical patch as claimed in claim 1 containing an amount of capsaicin or capsaicin analog effective for this use is applied~~ The topical patch as claimed in claim 18, in which the viscosity-increasing additive is ethylcellulose or hydropropylcellulose.
20. (Original) A method for the production of a topical patch as claimed in claim 1, which comprises dissolving the therapeutic compound in an amphiphilic solvent, adding this solution to a solution of a polysiloxane or the matrix constituents and dispersing, coating the resulting dispersion onto a protective layer which is removable again and removing the solvent of the polysiloxane and laminating the backing layer onto the dried matrix layer.